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# APPLICATION BRANCH DATA BASE ROUTING SLIP

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QUALITY CONTROL UNIT (PALM LOC 035)  
CP2-7C24

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FROM

Group, Office or Film 1641	PALM LOC Code ---
Person to Contact J Grun	
Phone no. <del>703-308-3980</del> 703-308-3980	

Application Serial No. 091515283
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Date Forwarded 10/14/2002
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For an inquiry on this correction  
(after 7 workdays) phone the  
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Correction Required: Continuity data needs updating to 8

" This Appln is a CIP of 08/957,098 10/24/1997 ABN "

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Application/Control Number: 09/515,283

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An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on 11 October 2002, Dr. Daniel S. Hodgins requested an extension of time for 1 MONTH(S) and authorized the Commissioner to charge Deposit Account No. 07-2400 /Dkt P6335.01CPA the required fee of \$ 55.00 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

IN THE SPECIFICATION:

Page 1, in the insert before the first line, after "1997", --, now abandoned-- was inserted.

Page 10, line 11, "ECTA" was corrected to --EDTA--.

Page 11, third full paragraph, "dihdrate" was deleted and --dihydrate-- inserted therefor.

IN THE ABSTRACT:

There being no abstract, the following was added:

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~~/~~ABSTRACT OF THE DISCLOSURE

E I  
Compositions and methods are described for enhancing the immunohistochemical staining of tissue samples. Compositions include a single solution, which includes at least one surfactant, adapted to remove an embedding medium of a tissue sample, rehydrate the tissue sample, and enhance the immunohistochemical staining of the tissue in relation to immunohistochemical staining of unreacted tissue. Methods include heating the tissue sample with the composition to enhance the immunohistochemical staining of the tissue. ~~/~~

IN THE CLAIMS:

Claim 54 was cancelled without prejudice or disclaimer thereto.

Claim 52, line 1, after "where", --the-- was inserted.

Claim 55, line 2, "Tris-HCl" was deleted and --tris(hydroxymethyl)aminomethane-- inserted therefor.

Claim 55, line 2, "EDTA" was deleted and --ethylenediaminetetraacetic acid-- inserted therefor.

Claim 55, line 2, "and" was deleted and --or-- inserted therefor.

Claim 56, line 1, "EDTA" was deleted and --ethylenediaminetetraacetic acid-- inserted therefor.

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<sup>1</sup>  
~~45.~~ (Twice Amended) A composition for enhancing antigenicity of a formaldehyde-fixed, paraffin-embedded, tissue, the composition being a buffered solution comprising:

[A buffered solution of ]about 0.01 moles of trisodium citrate dihydrate, [and ]about 1000 milliliters of water[;], and about 18.5 milliliters of a mixture having by weight about 5.8% ethylene glycol monobutyl ether, about 3.75% nonylphenol ethoxylate, about 1.5% tetrapotassium pyrophosphate and about 88.95% water; and

the [solution] composition having a pH [being] between about 5.96 and about 6.04.

<sup>2</sup>  
~~46.~~ (Twice Amended) An aqueous composition [having a pH being between about 5.96 and about 6.04] for enhancing antigenicity of a formaldehyde-fixed, paraffin-embedded, slide-mounted tissue, the composition having a pH between about 5.96 and about 6.04 and comprising:

greater than 0% and up to about 25% by volume of a mixture having by weight about 5.8% ethylene glycol monobutyl ether, about 3.75% nonylphenol ethoxylate, about 1.5% tetrapotassium pyrophosphate and about 88.95% water; and

greater than 0% and up to 10% by weight of citric acid and alkaline citrate salts.

<sup>3</sup>  
~~47.~~ (Twice Amended) A method for enhancing antigenicity using the composition of [C]claim <sup>1</sup>~~45~~ or <sup>2</sup>~~46~~, including the steps of:

contacting a formalin-fixed, paraffin-embedded tissue with the composition and heating to a temperature of at least 80°C for a time sufficient so that paraffin is removed from the tissue into the heated composition contacting the tissue and the tissue becomes substantially hydrated; thereafter removing the tissue from contact with the composition[; and] including washing the tissue to remove residual composition;

wherein the antigenicity of the contacted, heated, and washed tissue for immunochemical staining is enhanced over that of formalin-fixed, paraffin-embedded tissue not so contacted.

E2  
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4  
48. (Twice Amended) A method for enhancing immunochemical staining of a paraffin-embedded, formalin-fixed tissue with a single solution, the method comprising:

immersing said tissue for a period of at least about 10 minutes and a temperature of at least 80°C in an [up to about 10 weight percent] aqueous, [surfactant] paraffin-removing, tissue-activating agent solution having a pH from about 2 to about 8, said solution containing greater than 0% and up to about 10% by weight of at least one surfactant capable of, upon heating, removing paraffin from the tissue in contact therewith and also containing at least one tissue activating agent selected from [of] a buffer[, ] or a salt[ -tissue activating agent];

thereafter removing the tissue from the solution including washing the tissue to remove residual solution;

wherein the immunochemical staining of the immersed, heated, and washed tissue is enhanced over that of formalin-fixed, paraffin-embedded tissue not so immersed and heated.

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E3 <sup>7</sup>~~151~~. (Twice Amended) The method of claim <sup>4</sup>~~48~~ where the surfactant is at least one of a cationic, anionic, amphoteric, or [and] nonionic surfactant. ✓

E4 <sup>9</sup>~~153~~. (Twice Amended) The method of claim <sup>4</sup>~~48~~ where the tissue activating agent is at least one salt selected from the group consisting of aluminum chloride, sodium chloride, sodium fluoride, iron chloride, zinc sulfate, and lead thiocyanate. ✓

The following is an examiner's statement of reasons for allowance: the subject matter of applicant's instant claims, as amended, has been accorded the benefit of the 1997 filing date of the parent application, USSN 08/957,098. Therefore, the declarations under 37 CFR § 1.131 and 37 CFR § 1.132 and applicant's arguments thereto previously filed on 19 April 2002 have been found sufficient to overcome the Yörükoğlu et al and Cell Marque Corporation references and are found persuasive.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (703) 308-3980. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306, or (703) 305-3014, or (703) 308-4242. Official After Final communications, only, can be facsimile transmitted to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. The above inquiries, or requests to supply missing elements from Office communications, can also be directed to the TC 1600 Customer Service Office at phone numbers (703) 308-0197 or (703) 308-0198.



James L. Grun, Ph.D.  
October 13, 2002



CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800/641

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